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A Department of Energy Environmental Cleanup Program

Environmental Restoration Project Quality Procedure

for:

# Document Development and Approval Process: Peer Review Required



Los Alamos, New Mexico 87545

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## Document Development and Approval Process: Peer Review Required

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	List of Acronyms a	nd Abb	reviations				
AA	administrative authority	QP	quality procedure				
AOC	area of concern	RCRA	Resource Conservation and				
CMS	corrective measures study		Recovery Act of 1976				
DOE	US Department of Energy	RC	Regulatory Compliance Focus  Area				
DT	document team	RFI	RCRA facility investigation				
ER	environmental restoration	S-7	Classification Group				
IA	interim action	SAP	sampling and analysis plan				
IM	interim measure	SOP	standard operating procedure				
IWP	installation work plan	SOW	statement of work				
LA-UR	Los Alamos - Unlimited Release	TD	transmittal document				
LC	Laboratory Counsel	TIR	technical information release				
NMED	New Mexico Environment Department	URL	uniform resource locator				
РО	Project Office	VCA	voluntary corrective action				
PRS	potential release site	VCM	voluntary corrective measure				

### **Process: Peer Review Required**

**NOTE:** Environmental Restoration (ER) Project personnel may produce paper copies of this procedure printed from the controlled-document electronic file located at <a href="http://erinternal.lanl.gov/documents/procedures/qps.htm">http://erinternal.lanl.gov/documents/procedures/qps.htm</a>. However, it is their responsibility to ensure that they are trained on and utilizing the current version of this procedure. The Quality Program Project Leader may be contacted if text is unclear.

#### 1.0 PURPOSE

This Quality Procedure (QP) describes the Los Alamos National Laboratory (Laboratory) ER Project process for planning, developing, reviewing, and approving ER Project documents that require a peer review in accordance with QP-3.5, Peer Review Process (<a href="http://erinternal.lanl.gov/Quality/user/qps.asp">http://erinternal.lanl.gov/Quality/user/qps.asp</a>) (see Attachment A, Document Development and Approval Decision Process Flow Diagram, and Attachment B, Environmental Restoration Project Documents Matrix).

#### 2.0 DEFINITIONS

- 2.1 <u>Administrative authority</u> The New Mexico Environment Department (NMED), US Environmental Protection Agency, or the U.S. Department of Energy (DOE), as appropriate.
- 2.2 <u>Certification</u> A signed statement required by permits that is attached to all reports and to other information requested by the administrative authority (AA). Certification ensures that a document and all its attachments were prepared under the direction or supervision of an authorized person in accordance with a system designed to ensure that qualified personnel properly gather and evaluate the information submitted; it carries significant penalties for known violations [Permit Program, 27.11(b)(c)(d)].
- 2.3 <u>Decision peer review</u>— A review that occurs before document writing has begun. This review focuses on the appropriateness of the stated objectives for the identified program, adequacy of the proposed approach to address the objectives, and identification of concerns and necessary contingencies (see QP-3.5, Peer Review Process).
- 2.4 <u>Document</u> A written or pictorial compilation of information that describes, defines, specifies, reports, or certifies activities, requirements, procedures, or results (e.g., any plan, report, proposal, regulatory response, permit

- modification request, document addendum or update, or procedure) that must be submitted to AA or has significance to the operations of the ER Project. Representative document types are listed in Section 4.1.2 below and in Attachment B.
- 2.5 <u>Document peer review</u>— The review of a completed draft of a document that focuses on clarity of presentation and consistent, appropriate format and content in addition to appropriate approach. This review may be in the form of a panel review or a read review (reference QP-3.5, Peer Review Process).
- 2.6 <u>ER Project document catalog number</u> The unique document identifier, automatically assigned to a document when an on-line ER Project Document Signature Form is initiated, located at the following Web uniform resource locator (URL), <a href="http://erinternal.lanl.gov/DocCatalog/">http://erinternal.lanl.gov/DocCatalog/</a>.
- 2.7 <u>ER Project Document Signature Form</u> The form generated on-line, located at the following Web URL, <a href="http://erinternal.lanl.gov/DocCatalog/">http://erinternal.lanl.gov/DocCatalog/</a>, that documents the review and approval process for all internally developed documents and automatically acquires the document catalog number.
- 2.8 <u>Final document</u> This term refers to a document that is subject to the QP-4.9 (or QP-4.10) process and that
  - has addressed all comments from all required reviews;
  - has undergone a full edit;
  - is composited in accordance with current ER Project and Laboratory standards, if applicable;
  - has a completed ER Project Document Signature Form; and
  - is considered ready for submission to the AA, if applicable.
- 2.9 <u>Graded approach</u> A management tool used to evaluate the importance and relative risk of an item, activity, or service in the working process.
- 2.10 <u>Los Alamos unlimited release (LA-UR) number</u> The identification number required for all documents or presentations prepared for distribution outside the Laboratory. LA-UR numbers are attained by filling out a Technical Information Release (TIR) form located on the Laboratory network under documents, Web URL (<a href="http://enterprise.lanl.gov/alpha.htm">http://enterprise.lanl.gov/alpha.htm</a>) and submitting the form with a specified number of copies of the document to the Laboratory's Classification Group (S-7) for review.
- 2.11 <u>Required outline</u> A specified outline that dictates the format and content of documents; contact the Regulatory Compliance Focus Area (i.e., by e-mail, telephone, or as appropriate) for information about required outlines and guidance for preparing documents for which no required outline exists (also see Section 4.1.2 below for representative document types and/or Attachment B).

#### 3.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities based on a graded approach identified in Section 4.1 of this procedure.

- 3.1 Author
- 3.2 Document Team
- 3.3 ER Program Manager
- 3.4 ER Project, Project Office Administrator
- 3.5 ER Project Technical Writer/Editor
- 3.6 Team Leader
- 3.7 Technical Reviewers

#### 4.0 PROCEDURE

- 4.1 Graded Approach
  - 4.1.1 The following process describes the most rigorous requirements for document development, review, and approval. Attachment A, Document Development and Approval Decision Process Flow Diagram, demonstrates the document-development decision process. A graded approach (see Section 2.9 above), as determined by the author during document planning, is allowed based on the document type (see Section 4.1.2 below), size, and review/approval requirements depicted in Attachment B, Environmental Restoration Project Documents Matrix. If during the planning stages the author determines that he or she can meet all requirements without following each step below, the identified step may be omitted as appropriate.
  - 4.1.2 The following list identifies representative documents produced by the ER Project that require a peer review (follow QP-3.5). Note that the asterisk identifies the source, when it is available, of an official outline/template for a document type (also see Attachment B).

#### Representative Documents for External Distribution:

- Corrective Measures Study (CMS) Plan
- CMS Report
- Guidance Document
- Integrated Sampling and Analysis Plan (SAP)
- Interim Action (IA) Plan
- IA Report
- Interim Measures (IM) Plan

- IM Report
- Installation Work Plan (IWP) Update
- RCRA (Resource Conservation and Recovery Act) Facility Investigation (RFI) Work Plan\*
- REACH Report
- RFI Report (Phases 1 & 2)\*
- SAP\*
- SAP Addendum\*
- Technical Paper/Report
- Voluntary Corrective Action (VCA) Plan\*
- VCA Report\*
- Voluntary Corrective Measures (VCM) Plan\*
- VCM Report\*
- Well Completion Report (Performance-Measure Related)

#### Representative Documents for Internal Distribution:

- QP\*
- SAP (supplemental)\*
- Standard Operating Procedure (SOP)\*
- Statement of Work (SOW)

#### 4.2 Document Planning

#### 4.2.1 Appoint an Author

The **team leader** appoints an author to coordinate the planning, development, review, and approval of the document. However, the **team leader** supports the author throughout the document-development process.

4.2.2 Acquire the ER Project Document Signature Form

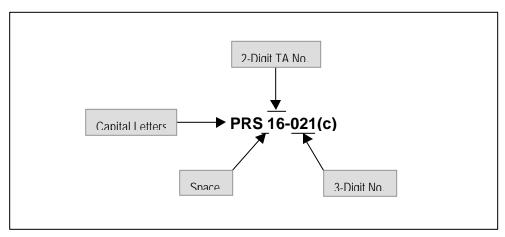
The **author** initiates the ER Project Document Signature Form that automatically acquires the ER Project document catalog number from the ER Project internal homepage located at the Web URL, <a href="http://erinternal.lanl.gov/DocCatalog/">http://erinternal.lanl.gov/DocCatalog/</a>; fills out the required and associated fields; and prints out the form.

**Note:** It is the author's responsibility to populate associated fields and acquire all required (see Attachment B) approval signatures on this ER Project Document Signature Form paper copy as he or she

<sup>\*</sup> http://erinternal.lanl.gov/home\_links/Library\_doctemp.htm

moves a document through the review and approval process steps defined in this QP.

**Note:** If a potential release site (PRS) delineation is required in the title and since all project information systems depend upon consistent PRS delineation to track project work, the proper format is demonstrated in Figure 4.2-1, below.



**Figure 4.2-1.** Proper configuration of the PRS number in a document title for an RFI report for PRS 16-021(c)

If you refer to more than one PRS, indicate them individually [e.g., PRS 03-005(a), PRS 03-005(b), and PRS 03-005(c), **not** PRS 03-005(a-c) or PRSs 03-005, -006]. In cases of areas of concern (AOCs), a capital "**C-**" designator precedes the two-digit TA identifier. If the PRSs are consolidated, add the consolidation number at the end of the configuration, [e.g., PRS 16-021(c)-99].

#### 4.2.3 Select the Document Team

4.2.3.1 The **author** selects a document team to assist in the preparation of the document. The document team may include the author; technical experts from appropriate fields; the Regulatory Compliance deployed person assigned to the focus area; a quality liaison; and/or an ER Project technical writer/editor.

**Note:** The assigned author uses his or her subject-matter expertise and judgment to determine if a required document is long enough and/or complex enough to require production by a team.

4.2.3.2 The **author** serves as the document team leader.

- 4.2.4 Determine the Document Requirements
  - 4.2.4.1 The **author** (with the assistance of the document team if convened) reviews and assesses the available information and determines what actions, decisions, and/or recommendations to implement in the development of the document (see Attachment B, Environmental Restoration Project Documents Matrix, for further information about a specific document type's review/approval requirements).
  - 4.2.4.2 The **author** (with the assistance of the document team if convened) plans the content of the document and determines whether a required outline exists for the type of document under development (see Section 4.1.2 above and/or Attachment B).

If a required outline	then the author
does not exist,	plans an outline to accommodate the document's objectives.
exists,	ensures compliance with this outline.

4.2.5 Determine the Need for a Decision Peer Review

The **author** determines if a decision peer review is required according to QP-3.5, Peer Review Process.

- **Note**: The author may contact the Peer Review Task Leader if uncertain about the need for a decision peer review.
- 4.2.6 Assign Tasks
  - 4.2.6.1 The author consults a technical writer/editor assigned to organizational area to help set achievable deadlines both in relation to the document's requirements and in relation to the deadlines of other documents that are in concurrent preparation.
  - 4.2.6.2 The **author** assigns document/section writing tasks to the members of the document team (if convened) and sets the deadline for the completion of the initial writing assignments.

#### 4.3 Document Development

4.3.1 Submit Document Sections

**Document team members** (if convened) ensure that their sections meet the requirements of the outline and submit completed sections to the author by the deadline for finishing assignments.

4.3.2 Submit Electronic File and/or Paper Copy

The **author** submits electronic files of the sections submitted by individual document team members, and paper copies of references not previously submitted in a reference set to the ER technical writer/editor to compile the entire document (including all appendices and attachments).

- 4.3.3 Edit and Compile Document
  - 4.3.3.1 From this point forward, the **ER Project technical** writer/editor is responsible for and coordinates the document (e.g., all the document's electronic files and the transmittal letter).
  - 4.3.3.2 The ER Project technical writer/editor labels all electronic files with the ER Project document catalog number, taken from the first line of the ER Project Document Signature Form, a file description, and its associated software suffix (e.g., ER2000-xxxx Transmittal Ltr.doc).
  - 4.3.3.3 The **ER Project technical writer/editor** conducts a full edit on the document including a definition check against the official Glossary and Supplemental Glossary (<a href="http://erinternal.lanl.gov/">http://erinternal.lanl.gov/</a>).
  - 4.3.3.4 The **ER Project technical writer/editor** enters the notation "Draft" and the ER Project document catalog number on the cover and in the footer of each page.
  - 4.3.3.5 The **ER Project technical writer/editor** compiles the edited document and provides a paper copy of the draft document to the author.
- 4.3.4 Complete the Technical Information Release Form

If the document is listed under "External Distribution" in Section 4.1.2 above and/or as shown in Attachment B, Environmental Restoration Project Documents Matrix, then concurrently with the above "full edit," the **author** ensures the completion of the TIR form located at the following Web URL, <a href="http://enterprise.lanl.gov/alpha.htm">http://enterprise.lanl.gov/alpha.htm</a>.

#### 4.3.5 Submit the Technical Information Release Form

The **author** ensures that the TIR and the appropriate number of copies of the draft document are submitted to the Laboratory's Classification Group (S-7) for review in time to meet scheduled deadlines and before Peer Review.

#### 4.4 Document Review and Approval

#### 4.4.1 Peer Review

#### 4.4.1.1 Compile the Draft Document

The **author** ensures that the ER Project technical writer/editor compiles the draft document for peer review in accordance with QP-3.5, Peer Review Process.

#### 4.4.1.2 Submit the Draft Document

The **ER Project technical writer/editor** provides a copy of the draft document to the author for peer review submission.

#### 4.4.1.3 Attach the ER Project Document Signature Form

The **author** ensures that the ER Project Document Signature Form is correctly updated and attached to the draft document.

#### 4.4.1.4 Request a Peer Review

The **team leader** requests a peer review, in accordance with QP-3.5, Peer Review Process; the team leader may review the draft document at this time.

#### 4.4.1.5 Perform Peer Review

The **author** submits the required copies of the complete, draft document for peer review in accordance with QP-3.5, Peer Review Process.

#### 4.4.1.6 Acquire Signatures

The **author** acquires the Peer Review Chair, ESH-19, and, if required, the regulatory compliance deployed reviewers' approval signatures on the ER Project Signature Form after peer review completion.

#### 4.4.2 Laboratory Counsel Review

4.4.2.1 If the document is listed under "Representative Documents for External Distribution" in Section 4.1.2 above and/or in Attachment B, Environmental Restoration Project Documents Matrix, the **author** ensures that review copies

are transmitted to Laboratory Counsel with a memorandum that is generated in accordance with the process from Section 4.2.2 above that includes the

- title of the document,
- source of the document,
- E/ER and focus area,
- due date for comments, and
- name and phone number of the contact person and ensures that the responsible team leader signs the memorandum.
- 4.4.2.2 The **author** references all related document catalog numbers in the appropriate field of the associated, on-line Signature Forms.
- 4.4.2.3 The **author** resolves the Laboratory Counsel reviewer's comments and marks all changes on a single paper or electronic copy (if coordinated in advance with the ER Project technical writer/editor).
- 4.4.2.4 The **ER Project technical writer/editor** ensures that the changes are incorporated into the document, edits the document at a level appropriate to address the changes, and ensures that the document is formatted appropriately.
- 4.4.2.5 The **ER Project technical writer/editor** provides a paper copy and/or an electronic copy of the revised draft to the author.
- 4.4.2.6 The **author** acquires Laboratory Counsel's approval signature on the ER Project Document Signature Form.
- **Note:** If Laboratory Counsel's review initiates major changes, the author repeats the peer review process (see Section 4.3.1 above).
- 4.4.3 Department of Energy (DOE) Review
  - 4.4.3.1 If required (reference Attachment B), the **author** ensures that review copies are transmitted to DOE with a transmittal letter that is generated in accordance with the process from Section 4.2.2 above and then references all associated, document catalog numbers in the appropriate fields of the associated, on-line Signature Forms.
  - **Note:** The DOE review schedule is as follows: if the document is a 1–100 page document, 10 working days; if 101–250 pages,

- 20 working days; and if over 250 pages, 30 working days before transmittal (see DOEAL/ERD-980002, 9/10/98, ER ID # 59895).
- 4.4.3.2 The author resolves the DOE reviewers' comments and marks all changes on a single paper or electronic copy (if coordinated in advance with the ER Project technical writer/editor).
- 4.4.3.3 The **ER Project technical writer/editor** ensures that the changes are incorporated into the document, edits the document at a level appropriate to address the changes, and ensures that the document is formatted appropriately.
- 4.4.3.4 The **ER Project technical writer/editor** provides a paper copy and/or an electronic copy of the revised draft to the author.
- 4.4.3.5 The **author** acquires the DOE-reviewer's approval signature on the ER Project Document Signature Form.
- **Note:** If DOE review initiates major changes, the author repeats the peer review process in accordance to Section 4.4.1, above.
- 4.4.4 Draft the Transmittal Letter

If required, the **author** drafts a transmittal letter (in accordance with Section 4.2.2 above) that addresses all necessary requirements (if performance-measure-related, also see DI-4.5, Review and Approval of Performance-Measure-Related Documents) and then ensures that all references to associated document catalog numbers are inserted in the appropriate field of all associated, Document Signature Forms.

- 4.4.5 Verify Proper Document Development
  - 4.4.5.1 The **author** ensures that all of the requirements in this QP are met, including the population of all required and associated fields in the Document Signature Form (e.g., LA-UR#, associated catalog numbers, etc.).
  - 4.4.5.2 The **author** attests to the document's completeness and accuracy with an approval signature on the ER Project Document Signature Form.
  - 4.4.5.3 The **author** sends the ER Project Document Signature Form and the final draft document, including the draft transmittal letter, to the team leader.

- 4.4.5.4 The **team leader** ensures that the document was developed according to requirements with an approval signature on the ER Project Document Signature Form.
- 4.4.5.5 At this point the document becomes final and the **author** ensures that all draft designations are removed from what was the "Final Draft" document.
- **Note:** Some documents (e.g., the IWP) maintain the "draft" designation for ER project document citation purposes pending AA approvals. After AA approval, the document is given a revision number in order to distinguish between previously-cited documents.
- 4.4.5.6 The **author** ensures that all documents, paper and electronic copies, are identified with the ER Project document catalog number as the first designation; **one** electronic copy is appropriate for submittal to the Record Processing Facility (RPF) saved as the associated software (e.g., .doc, .xls, etc.). (See Attachment C for the electronic file submission process.)
- 4.4.5.7 The **author** transmits a copy of the final document to Classification (S-7) with a cover memorandum (produced in accordance to Section 4.2.2 above).
- 4.4.5.8 The **author** ensures that a paper copy of the final document is transmitted to the peer review coordinator.
- 4.4.6 Initiate the Project Office Review/Approval Process
  - 4.4.6.1 The **author** sends the document to the ER Project, project office administrator.
  - 4.4.6.2 If the document is performance-measure related, the **project office administrator** follows DI-4.5, Review and Approval of
    Performance-Measure-Related Documents.
  - 4.4.6.3 If the document is **not** performance-measure related, the **project office administrator** follows the PO established process.
  - 4.4.6.4 If the document is listed under "Representative Documents for External Distribution" in Section 4.1.2 above and/or in Attachment B, the **author** ensures that a copy of the document, without enclosures, is submitted to the Deliverable Tracking and Closeout Team of the Regulatory Compliance Focus Area.

#### 5.0 RECORDS

The **author** ensures that the following records are submitted according to QP-4.4, Record Transmittal to the Records Processing Facility.

- 5.1 The final document (paper copy)
- 5.2 The final document electronic files

**Note:** The electronic file is named with the ER Project document catalog number as the first designation and saved as its associated software file (e.g., .doc, .xls, etc.). (See Attachment C, ER Project Electronic File Capture Process Flow Diagram.)

- 5.3 Completed ER Project Document Signature Forms
- 5.4 Transmittal letters (if the graded approach requires)
- 5.5 Memoranda (if the graded approach requires)
- 5.6 The certification (if the graded approach requires)
- 5.7 Documents referenced within the document that do not currently reside in the RPF (if applicable)
- 5.8 Documentation of reviewer nonconcurrences with comment resolutions (if applicable)

#### 6.0 TRAINING

All users of this QP are trained by self-study, and the training is documented in accordance with QP-2.2, Personnel Orientation and Training.

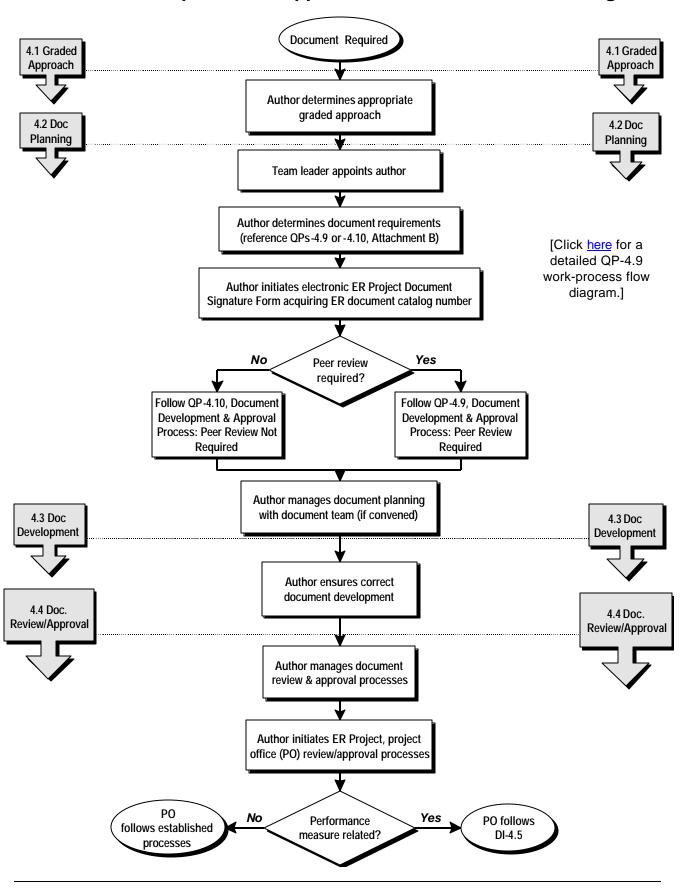
#### 7.0 ATTACHMENTS

Attachment A: Document Development and Approval Decision Process Flow Diagram (1 page)

Attachment B: Environmental Restoration Project Documents Matrix (1 page)

Attachment C: ER Project Electronic File Capture Process Flow Diagram (1 page)

#### **Document Development and Approval Decision Process Flow Diagram**



		Environ	mental Rest	toration Pro	ject Docum	ents Matrix				
	REVIEW / SIGNATURE REQUIRED				SIGNATURE REQUIRED			S-7	CERTIFICATION	
DOCUMENT	PEER REVIEW	ESH-19	REGULATORY	Laboratory	DOE-LAAO	Focus Area	DOE-LAAO	<b>ER PROGRAM</b>	(LA-UR#)	
	CHAIR	LJII-17	COMPLIANCE	Counsel	DOL-LAAO	Leader	Prog. Mgr.	MANAGER	(LA-UK#)	KEQUIKED
			Peer	REVIEW REQUIRED	(QP-4.9)					
External Distribution:										
CMS Work Plan	•	•	•	•	•	<b>*</b>	<b>*</b>	•	<b>*</b>	•
CMS Report	<b>*</b>	<b>*</b>	•	<b>*</b>	•	<b>*</b>	•	<b>*</b>	<b>*</b>	<b>*</b>
Guidance Document	•	<b>*</b>	•	<b>*</b>	•	<b>*</b>	<b>*</b>	<b>*</b>	•	
Interim Action Plan	•	•	•	•	•	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>	
Interim Action Report	•	<b>*</b>	•	•	•	<b>*</b>	<b>•</b>	<b>*</b>	<b>*</b>	
Interim Measures Plan	•	<b>*</b>	•	•	•	<b>*</b>	<b>•</b>	<b>*</b>	<b>*</b>	
Interim Measures Report	•	•	•	•	•	<b>*</b>	•	<b>*</b>	•	
IWP Update	•	<b>*</b>	•	<b>*</b>	•	<b>*</b>	<b>*</b>	<b>*</b>	•	<b>*</b>
RCRA RFI Work Plan*	•	•	•	•	•	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>
Reach Report	•	•	•	•	•	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>
RFI Report (Phase 1 & 2)*	•	•	•	•	•	•	•	<b>*</b>	•	<b>*</b>
SAP & SAP Addendum*	•	•	•	•	•	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>	
Technical Paper/Report	•	•	•	•	•	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>	
VCA Plan*	<b>*</b>	<b>*</b>	•	<b>*</b>	•	<b>*</b>	•	<b>*</b>	<b>*</b>	
VCA Report*	•	•	•	•	•	•	•	<b>*</b>	•	<b>*</b>
VCM Plan*	•	•	•	•	•	<b>*</b>	<b>*</b>	<b>*</b>	<b>*</b>	
VCM Report*	•	<b>*</b>	•	•	•	<b>*</b>	<b>•</b>	<b>*</b>	<b>*</b>	<b>*</b>
Well Completion Report (PM related)	<b>*</b>	<b>*</b>	•	<b>*</b>	•	<b>*</b>	•	<b>*</b>	<b>*</b>	
Internal Distribution:										
QP*	•							•		
SAP (supplemental)	<b>*</b>							<b>*</b>		
SOP*	•									
SOW	•									
	<u> </u>		Peer Re	VIEW NOT REQUIR	ED (QP-4.10)			<u>,                                      </u>		
External Distribution:										
AA-Negotiated Document		•	•	•	•		•	<b>*</b>	•	
ER Quarterly Technical Report		•	•	•	•		•	<b>*</b>	•	<b>*</b>
Monthly CMS Progress Report		•	•	•	•	•	•	•	•	
Permit Modification		•	•	•	•		•	•	<b>*</b>	<b>*</b>
Transmittal Letter						•	•	•		
Accelerated Process / External:										
Compliance Order Response		•	•	•	•			•	•	•
NOD Response*		•	•	•	•			•	•	<b>*</b>
RSI Response*		•	•	•	•			•	•	
Internal Distribution:										
Desk Instruction*										
Directive (internal)			İ					•		
Memorandum	1		Ì	1				•		

<sup>\*</sup> Available outline/template: http://erinternal.lanl.gov/home\_links/Library\_doctemp.htm.

